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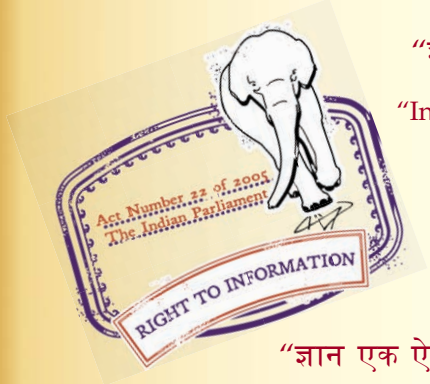
IS 10012 (1981): Dental Zinc Oxide/Eugenol Filling Materials [MHD 8: Dentistry]



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IS : 10012 - 1981
(Reaffirmed 1998)

Indian Standard

SPECIFICATION FOR DENTAL ZINC OXIDE/EUGENOL FILLING MATERIALS

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NEW DELHI 110002

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Indian Standard

SPECIFICATION FOR DENTAL ZINC OXIDE/EUGENOL FILLING MATERIALS

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SPECIFICATION FOR DENTAL ZINC OXIDE/EUGENOL FILLING MATERIALS

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 18 November 1981, after the draft finalized by the Dental Materials Sectional Committee had been approved by the Chemical Division Council.

0.2 Zinc oxide/eugenol filling materials are intended for use in the oral cavity. The material is used as cavity linings and bases, temporary and root-canal fillings.

0.3 This standard substantially agrees with ISO 3106-1974 Dental zinc oxide/eugenol filling materials, published by International Organization for Standardization (ISO).

0.4 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard prescribes the requirements and the methods of sampling and test for zinc oxide/eugenol filling materials supplied as two separate components.

2. TYPES

2.1 The material shall be of two types, namely.

a) Type 1 — Fast setting, and

b) Type 2 -- Normal setting.

*Rules for rounding off numerical values (*revised*).

3. REQUIREMENTS

3.1 Components

3.1.1 General-The components, when mixed in accordance with the manufacturer's instructions, shall set rapidly to a condition suitable for the intended dental use.

3.1.2 *Liquid* — The liquid shall be clear with a light amber tinge, and free from suspended matter, deposit or sediment.

3.1.3 *Powder* — The powder shall be free of extraneous material. When coloured, the pigment shall be uniformly dispersed throughout the powder.

3.1.4 *Purity of Ingredients-The* quality of the ingredients used in the manufacture of the cement components shall conform to the national pharmacopoeia standards of purity, or such regulations as arc applicable to the purity of pharmaceutical products.

3.2 Physical Properties

3.2.1 *Consistency* -- The consistency of the material, when determined in accordance with A-2, shall be 25 ± 1 mm in terms of the disc diameter.

3.2.2 *Setting 'Time* — The setting time of the material, when determined in accordance with A-3, shall be as follows:

Type 1 — 3 to 5·5 min,
Type 2 — 4·5 to 7 min.

3.2.3 *Compressive Strength* — The compressive strength of the cement 24 h after mixing, when determined in accordance with A-4, shall not be less than 25 MN/m^2.

3.2.4 *Solubility and Disintegration* — The amount of non-volatile matter of the material, when determined in accordance with A-5, shall not be more than 0·5 percent by mass, after immersion for 23 h.

4. PACKING AND MARKING

4.1 Packing-The components shall be supplied in securely sealed containers made from materials which do not react with or permit contamination of the contents.

4.2 **Marking** — Each container shall bear legibly and indelibly the following information :

a) Name and type of the material;
b) Name of' the manufacturer and/or his recognized trade-mark, if any;
c) Net mass in g of the powder and net volume in ml of the liquid; and
d) Batch number.

4.2.1 *Information to be Supplied by the Manufacturer* — Adequate instructions for guidance of the user in proportioning, mixing and manipulation shall accompany each container. The following details shall be included:

a) the recommended tctnperature and humidity for mixing and condition and type of mixing surface,
b) an appropriate component ratio under the recommended ambient conditions, and
c) the rate of incorporation of one component with the other and the maximum mixing time.

4.2.2 The containers may also be marked with the IS1 Certification Mark.

NOTE — **The use of** the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The IS1 Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

5. SAMPLING

5.1 Kepresentativc samples of the material shall be drawn as prescribed in Appendix B.

APPENDIX A
(*Clause* **3.2**)

METHODS OF TEST FOR **ZINC OXIDE/EUGENOL FILLING MATERIALS**

A-l. PREPARATION OF TEST SPECIMENS

A-l.1 Ambient Conditions — Carry out all mixing of the material for the preparation of the test specimens at a temperature of $27 \pm 2°C$ and a relative humidity of 65 ± 5 percent.

A-l.2 Mixing

A-1.2.1 *Apparatus*

A-1.2.1.1 *Smooth glass slab* — approximately 150 x 75 x *20* mm.

A-1.2.1.2 *Rigid spatula* — With a blade having dimensions approximately 45 x 8 mm, made from a material not affected by the cement.

A-1.2.2 *Procedure*

A-1.2.2.1 Before the commencement of mixing, condition the test samples and apparatus under the ambient conditions specified in **A-1.1,** except where stated otherwise.

A-1.2.2.2 Place on the glass slab the correct mass of powder and volume of liquid, as determined by the consistency test (*see* A-2) and divide into four portions as follows:

a) Divide the powder approximately in two halves,

b) Divide one half into two quarters,

c) Divide one quarter into two eights.

Mix the material by incorporating the half-portion of the powder into the liquid in the first 15 s, then the quarter and eight-portions, each at 15 s intervals, each portion being mixed thoroughly before introducing the next portion. Then spatulate the whole mass with reasonable pressure for a further 15 s, utilizing approximately one-third of the top surface of the glass slab. The total mixing time shall be 1·25 min.

Leave no powder or liquid on the slab when the mixing has been completed.

A-2. CONSISTENCY

A-2.1 Apparatus

A-2.1.1 *Load* — *of* mass *2* 480 ± 5 g mounted on a loading device such as that shown in Fig. 1, in such a manner as to allow essentially frictionless movement in a vertical direction.

A-2.1.2 *Two Class Plates* — *of* minimum dimensions 30 x 30 mm, one having a mass of 20 ± 2 g.

A-2.1.3 *Graduated Hypodermic-Type Syringe* — capacity 0·50 ml, with an accuracy of ± 0.005 ml.

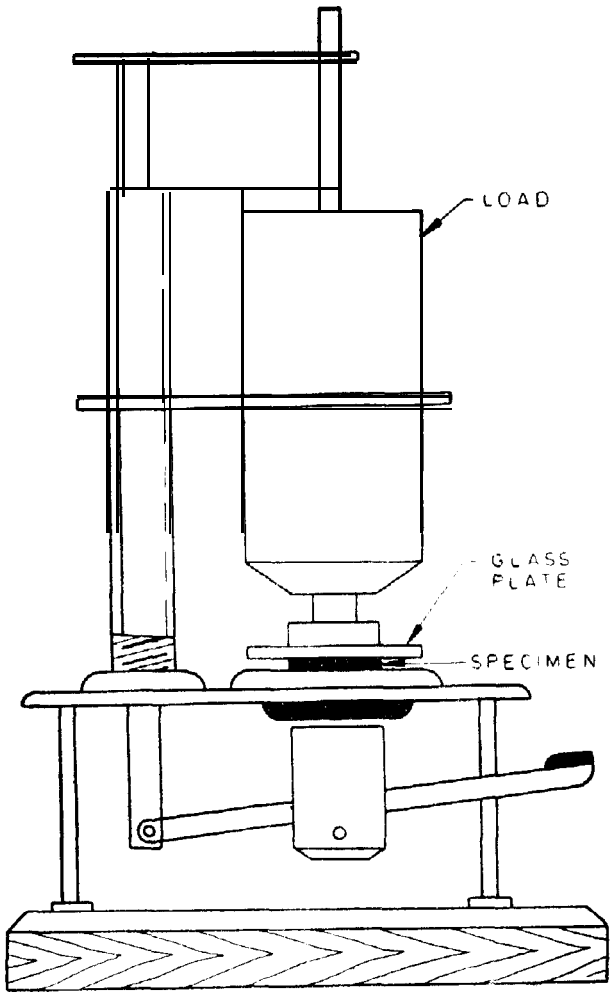


FIG. 1 LOADING DEVICE FOR USE IN CONSISTENCY DETERMINATION

A-2.1.4 *Measuring* Device — designed to deliver $0{\cdot}50 \pm 0{\cdot}05$ ml of mixed cement.

A suitable device is illustrated in Fig. 2 and comprises:

a) a glass tube with internal diameter approximately 10 mm;

b) a gauge-plug and plunger,

c) a rubber or plastics plug, and polyethylene disc (maximum thickness of polyethylene disc 0·10 mm).

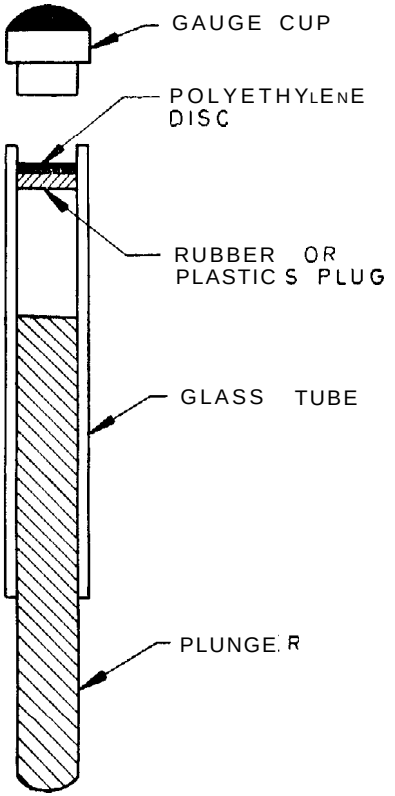


FIG. 2 **MEASURING DEVICE FOR USE IN CONSISTENCY DETERMINATION**

A-2.2 **Preparation of Components** — Carefully weigh a trial amount of powder and place at one end of the glass slab. Using the graduated syringe, deposit 0·40 ml of liquid towards the other end of the slab with at least half the length of the slab separating it from the powder.

Mix the powder and liquid in accordance with A-1.2.2.2 and at the conclusion of mixing collect the cement in a convenient mass on the glass slab.

A-2.3 Procedure

A-2.3.1 Completely fill the end of the glass tube with cement, with the rubber or plastics plug and polyethylene disc in position to measure 0·5 ml of the cement by volume. (Two or three shallow V-cuts along the side of the plug will, if the plug is slightly over-sized, ensure a tight fit and prevent air from being trapped during the filling operation.) Carefully extrude the measured quantity (0·5 ml) of each mix from the glass measuring device into the glass plate, taking care to avoid mis-shaping the cylindrical form of the resultant cement specimen. Allow the polyethylene disc to stay in place.

A-2.3.2 Place the cement resting on the glass plate in position on the loading devices, so that t he cement is centrally below the supported 2 480 g mass. Two minutes after the commencement of mixing, lower the top glass plate, with a mass of 20 g, and the mass of 2 480 g (a total load of mass 2 500 g) gently onto the cement and allow it to remain there for 5 min.

NOTE — It is essential during this testing procedure that the glass plates arc maintained parallel to each other and that no rotary movement is allowed to take place.

A-2.3.3 Measure the resulting disc across two diameters at right angles to each other and average the two measurements, if t hey agree within 1 mm, to give a mean diameter. If the disc is not uniformly circular or if the results do not agree within 1 mm, repeat the test. Make trial mixes to known component ratios at a temperature of 27 ± 2°C and relative humidity of 65 ± 5 percent until a standard consistency disc is formed with a mean diameter of 25 ± 1 mm.

NOTE — The cement disc may he measured with or without the top glass plate in position. If it is intended to remove the top plate, then allow the cement to harden completely before doing so.

A-2.3.4 The placing of some form of graph paper (the polar graph type is very suitable) under the lower glass plate is strongly recommended as an aid to the rapid and accurate reading of the disc diameter.

A-2.4 **Calculation** -- Take t he average of three determinations and express the results in g/ml rounded off to the nearest 0·05 g/ml. Refer the ratio as the component ratio on testing consistency for the material under test.

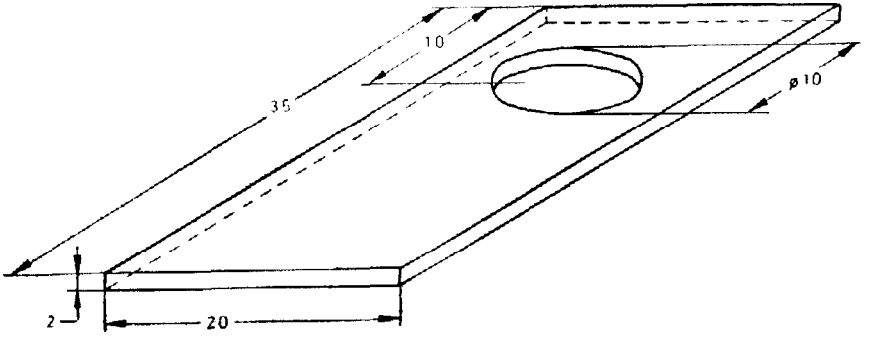
A-3. SETTING TIME

A-3.1 Apparatus

A-3.1.1 Oven — maintained at a temperature of 37 ± 1°C and a relative humidity of not less than 90 percent.

A-3.1.2 *Gillmore-Type Needle* with a mass of 450 ± 5 g, having a flat rnd of $1{\cdot}00 \pm 0{\cdot}05$ mm diameter, with the needle cylindrical for a distance of 2·5 mm from its end and the needle end plane and at right angles to the axis of the rod maintained in a clean condition.

A-3.1.3 *Brass Mould* — consisting of a rectangular plate with a circular hole conforming to dimensions given in Fig. 3.



All dimensions in millimetres.

FIG. 3 MOULD FOR USE IN DETERMINATION OF SETTING **TIME**

NOTE — The asymmetrical form of the mould has been designed for ease of handling.

A-3.1.4 *Metal Block* — of minimum dimensions 8 x 20 **x** 10 mm either as part of **A-3.1.1** or **A-3.1.2 or** else as a separate item.

A-3.1.5 *Flat* Glass *Plate* — approximately 1 mm thick (microscope slides are suitable).

A-3.2 Preparation of Test Specimen-Place the mould on the flat plate and fill with cement of standard consistency to a level surface. Two minutes after the commencement of mixing, place this assembly on the metal block which has been conditioned in the oven to a temperature of 37°C.

A-3.3 Procedure --- Two and a half minutes after the commencement of mixing, carefully lower the Gillmore-type needle vertically onto the horizontal surface of the cement which is still retained in the oven at 37°C. Repeat at 15 second interval near the time nf setting.

Record the time of setting as the period of time which elapses from commencement of mixing to the time when the needle fails to completely penetrate the 2 mm depth of the cement contained in the mould. This penetration can be confirmed by holding the specimen up to light and examining visually. Repeat this test once.

A-3.4 **Calculation** -- Calculate the average of two determinations and record the result to the nearest 15 s as the setting time.

A-4. COMPRESSIVE STRENGTH

A-4.1 Apparatus

A-4.1.1 *Oven* — maintained at a temperature of 37±1°C.

A-4.1.2 *Five Moulds and Plates* - such as those shown in Fig. 4, 12 mm high and 6 mm internal diameter, made of stainless steel or some other suitable material which is not attacked or corroded by the cement.

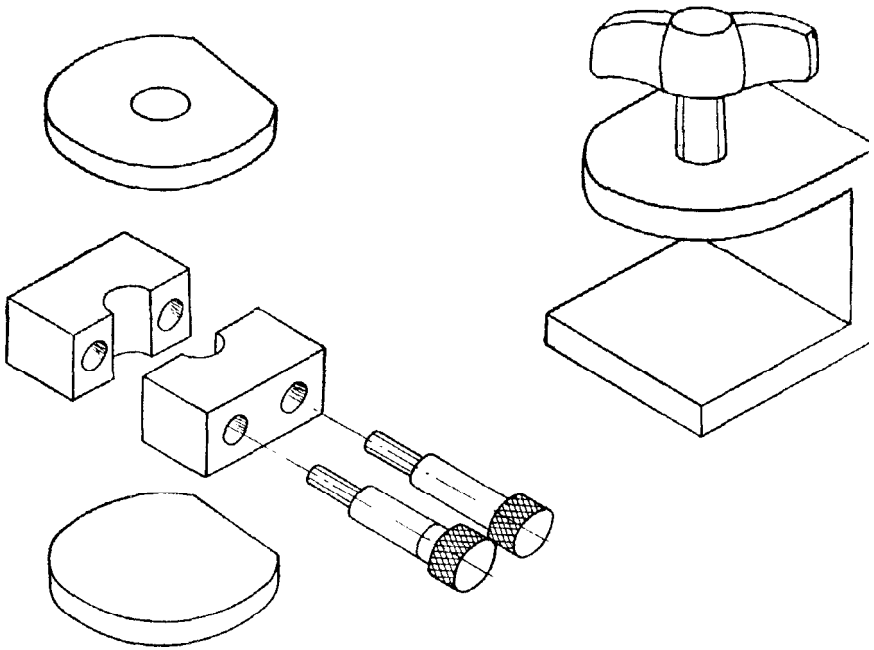


FIG. 4 MOULD AND CLAMP FOR PREPARATION OF COMPRESSIVE STRENGTH TEST SPECIMENS

A-4.1.3 *Five Individual Screw-Type Clamps* — such as those shown in Fig. 4.

A-4.1.4 Compressive Strength Testing Apparatus — having a cross-head speed of 1·50 ± 0·75 mm/min.

A-4.2 **Preparation of Test Specimens**

A-4.2.1 Condition the moulds and top and bottom plates at the ambient testing temperature (see **A-1.1)** and the clamps at 37°C.

A-4.2.2 Using a suitable spatula pack a slight excess of the material, mixed to the standard testing consistency, into the mould within 2 min of commencing mixing. In order to avoid trapping air and to facilitate consolidation of the cement, it is advisable to convey to the mould the largest convenient portion of the mix and to apply with the spatula to the side of the mould with the mould open at each end. Then firmly place the mould on the bottom metal plate and remove any bulk extruded excess of cement. Place the top metal plate in position and squeeze the assembly tightly together with the screw clamp. Three minutes after commencing mixing, transfer the assembly to the oven maintained at a temperature of 37°C. One hour after commencing mixing, remove the metal plates and surface the ends of the specimen plane at right angles to their long axes.

A-4.2.3 Surface the ends of the hardened cement specimen and remove any excess cement by grinding *on a glass* plate with a small amount of 45 μm silicon carbide, or some other suitable abrasive powder mixed with water. Alternatively, an equivalent abrasive paper, suitably supported, may be used. Draw the mould containing the cement specimen back and forth across the plate and rotate about one quarter-turn every few strokes. During the grinding operation, keep both ends of the specimen wet. Immediately after surfacing, remove the cement specimen from the mould.

NOTE — To facilitate the removal of the hardened cement, the internal surfaces of the mould may be coated evenly, prior to filling, with a thin (3 percent) solution of micro-crystalline or paraffin wax in pure toluene. Alternatively, a thin film of silicone grease or PTFE dry film lubricant may be used.

Rapidly check the test specimen for air voids or chipped edges and if found, discard the specimen. Immerse the specimen in distilled water maintained at 37 ± 1°C for 23 h. Prepare at least five such test specimens.

A-4.3 **Procedure** — Twenty-four hours after commencing mixing, determine the compressive strength of the specimens by means of a compressive strength testing apparatus. Place the test specimen with its flat ends between the anvils of the testing apparatus, so that the load is applied to the long axis of the test specimen. Record the maximum load applied when the specimen fractures, in newtons.

A-4.4 Calculation — calculate the compressive strength C, in meganewtons per square metre (newtons per square millimetre), by the following formula:

$$C = \frac{4P}{\pi d^2}$$

where

P = maximum applied load, in newtons; and

d = diameter in mm of the test specimen.

A total of five tests shall be carried out and the values obtained rounded off to the nearest whole number (in the case of 0·5 values, round up to the higher whole number). The mean of these five values shall be recorded as the test result.

A-5. SOLUBILITY AND DISINTEGRATION

A-5.1 Apparatus

A-5.1.1 *Oven* maintained at a temperature of 37±1°C.

A-5.1.2 *Mould* consisting of a split brass or stainless steel ring contained in a former as illustrated in Fig. 5, the wall thickness of the ring being 1 mm and the internal dimensions 20 mm diameter, and 1·5 mm depth.

A-5.1.3 *Platinum* Wire — or an equivalent non-corrosive material.

A-5.1.4 *Three Tared Glass Weighing Bottler* – such as those shown in Fig. 6.

A-5.1.5 *Multiple Spring Clamp* — *such* as that shown in Fig. 7. Condition the spring clamp by placing it in the oven at least 5 min before preparing the test specimen. Do not remove until required for insertion of individual specimens.

A-5.2 **Preparation of Test Specimens**

A-5.2.1 Place the mould on a thin polyethylene or cellulose acetate sheet backed by a flat glass plate. Weigh a convenient length of platinum wire and insert through the split in the ring, so that at least 10 mm projects into the ring.. Place a slight excess of the cement mixed to a stanclartl testing consistency in the mould and press another flat glass plate faced with a sheet of thin polyethylene or cellulose acetate on top of it. Hold the whole assembly firmly together with the spring clamp. Three minutes after the commencement of mixing, place the assembly in the oven maintained al a temperature of 37°C. One hour later remove the assembly, separate the glass plates and polyethylene or cellulose acetate sheets and carefully take the cement disc with attached wire from the **split ring.**

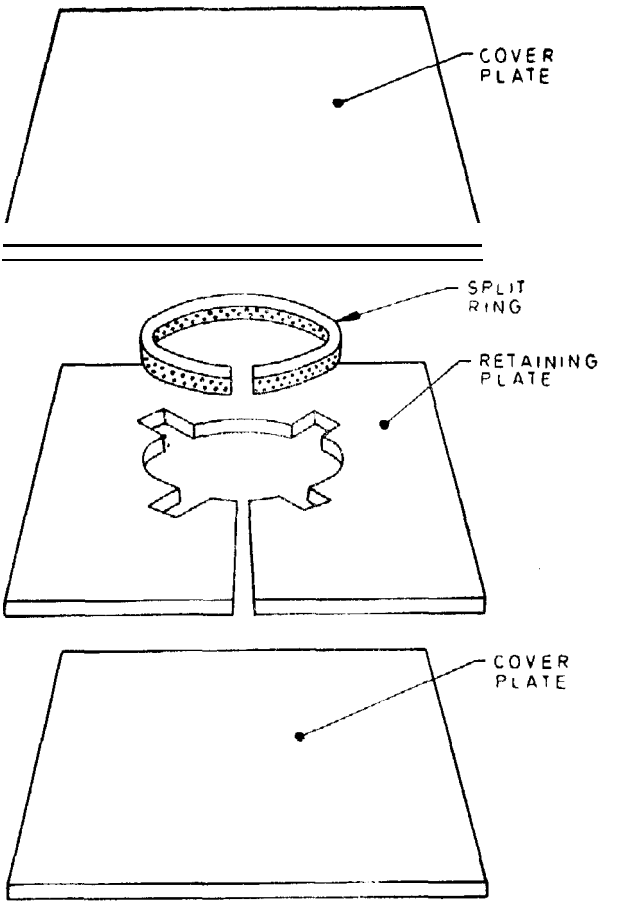


FIG. 5 MOULD FOR PREPARATION OF TEST SPECIMEN USED IN SOLUBILITY DETERMINATION

NOTE — Due Lo the comparatively brittle nature of some cements at this early hardening stage, it is essential to clean any excess cement from the surface of the split-ring before attempting removal of the specimens. It is also recommended that a suitable release agent be used on the split ring to facilitate removal of thr specimen from the mould. PTFE dry film lubricant is suggested.

A-5.2.2

speci-brush any loose material from the surface. Prepare two such mens for each determination.

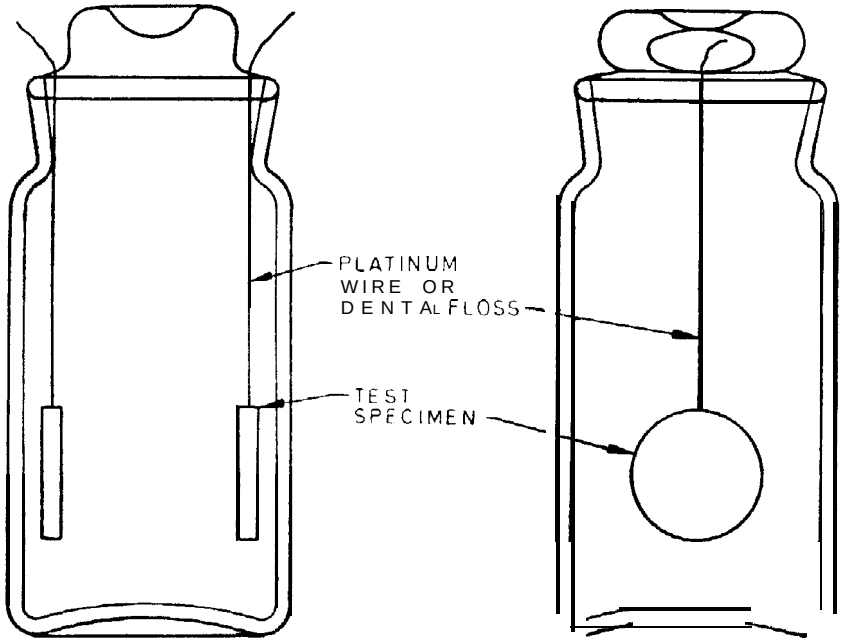


FIG. 6 WEIGHING BOTTLE CONTAINING SOLUBILITY SPECIMEN

A-5.3 Procedure

A-5.3.1 Place the two test specimens in a tared weighing bottle which has been previously conditioned to constant mass (reading A), and weigh the whole assembly. Take the combined mass of the two cement disc specimens and the weighing bottle less the mass of the weighing bottle and the platinum wire as the mass of the cement specimens.

A-5.3.2 Immediately submerge the two discs by pouring **50** ml of distilled water into the weighing bottle and then store for 23 h at 37 ± 1°C. Suspend the specimens by the wire, so that they neither touch each other nor rest against the side of the bottle and close the bottle lid as tightly as possible.

A-5.3.3 Twenty-four hours after the commencement of mixing, remove the specimens from the water. Evaporate the water from the weighing bottle at a temperature just below 100°C and dry the weighing bottle in an oven at 150°C for 24 h. After cooling to room temperature in a desiccator containing a suitable desiccant, weigh the weighing bottle and contents with a precision of 0·1mg (reading B).

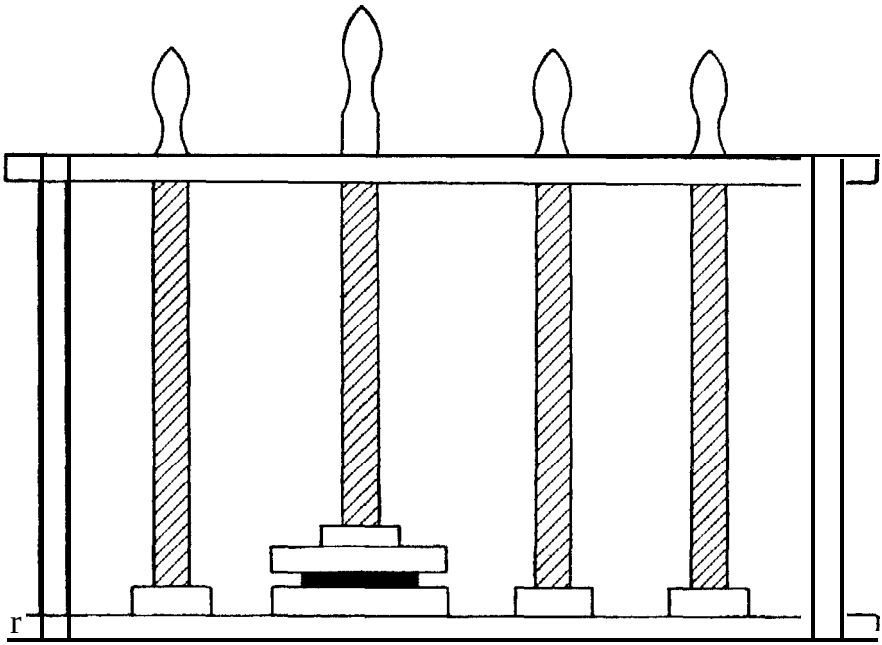


FIG. 7 MULTIPLE SPRING CLAMP

Carry out the test with a bottle containing **50** ml of distilled water as a control. Subject the bottle and contents to all steps of the test procedure and apply the blank correction.

A-5.4 **Calculation** — The solubility S, expressed as a percentage by mass, is given by the following formula:

$$S = \frac{\text{Keading } B - \text{Keading A}}{\text{Mass of cement specimens}} \times 100$$

The average of duplicate tests (two weighing bottles containing two specimens each) shall be reported to the nearest 0·01 percent.

APPENDIX B
(Clause 5.1)

SAMPLING OF ZINC OXIDE/EUGENOL FILLING MATERIALS

B-l. GENERAL REQUIREMENTS OF SAMPLING

B-1.0 In drawing, preparing, storing and handling test samples, the following precautions and directions shall be observecl.

B-l.1 Samples shall not be taken in an exposed place.

B-l.2 The sampling instrument shall be clean and dry.

B-1.3 Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the containers for samples from adventitious contamination.

B-l.4 To draw a representative sample, the contents of each container selected for sampling shall be mixed as thoroughly as possible by suitable means.

B-l.5 The samples shall be placed in clean, dry, air-tight glass or other suitable containers.

B-l.6 The sample containers shall be of such size that they are almost completely filled by the sample.

B-l.7 Each sample container shall be sealed air-tight with a suitable stopper after filling, and marked with full details of sampling, the date of sampling and the year of manufacture of the material.

B-2. SCALE OF SAMPLING

B-2.1 Lot — All the containers of one type in a single consignment of the material drawn from a single batch of manufacture shall constitute a Iot. If a consignment is declared or known to consist of different batches of manufacture, the containers belonging to the same batch shall be grouped together and each such group shall constitute a separate lot.

B-2.1.1 Samples shall be tested from each lot for ascertaining conformity of the material IO the requirements of this specification.

B-2.2 The number ofcontainers (n) to be chosen from the lot shall depend on the size of the lot (N) and shall be as given in Table 1.

TABLE 1 NUMBER OF CONTAINERS TO BE SELECTED FOR SAMPLING

LOT SIZE (N)	NUMBER OF CONTAINERS TO BE SELECTED (n)
(1)	(2)
3 to 50	3
51 to 200	4
201 to 400	5
401 to 650	6
651 to 1 000	7
1 001 and above	8

B-2.3 The containers to bc selected shall be chosen at random from the lot and in order to ensure the randomness of selection, the random sampling methods given in IS :4905-1968* may be followed.

B-3. TEST SAMPLES AND REFEREE SAMPLE

B-3.1 Preparation of Test Samples

B-3.1.1 *Liquid Component* — Empty the contents of all the sample containers selected into a clean glass-stoppered bottle. Mix the contents thoroughly and divide the composite sample into three equal parts, one for the purchaser, another for the supplier and the third for the referee.

B-3.1.2 *Solid Component* — Empty the contents of all the sample containers selected into a square-sided jar having a capacity of 2 litres and a self-sealing cap. Rotate the jar on its minor axis for 2 h at the rate of 25 rpm. Divide the composite sample into three equal parts, one for the purchaser, another for the supplier and the third for the referee.

B-3.2 Referee Sample — The referee sample shall consist of one composite sample each of the solid component and the liquid component, marked for this purpose, and shall bear the seals of the purchaser and the supplier. These shall be kept at a place agreed to between the purchaser and the supplier and shall be used in case of dispute.

*Methods for random sampling.

B-4. NUMBER OF TESTS

B-4.1 Tests for all the characteristics given in 3 shall be conducted on the composite sample.

B-5. CRITERIA FOR CONFORMITY

B-5.1 A lot shall be declared as conforming to this specification if the composite sample satisfies the requirements for each of the characteristics given in 3. If the requirements for any of the characteristics are not met, the lot shall be declared not to have satisfied the requirements of the specification.

INDIAN STANDARDS

ON

DENTAL MATERIALS AND ALLIED PRODUCTS

IS:

3571-1966 Dental gold solders
3578-1966 Dental gold alloy wire
3610-1966 Dental gold foil
4704-1968 Silver-tin dental amalgam alloy
4705-1968 Dental mercury
4799-1968 Dental casting gold alloys
5954-1970 Dental white gold alloys
6035-1970 Zinc phosphate dental cement
6036-1970 Alginate dental impression material
6037-1970 Zinc oxide-eugenol dental impression paste
6038-1970 Dental impression compound
6039-1970 Zinc oxide-eugenol dental cement
6043-1970 Copper phosphate-zinc phosphate dental cement
6555-1972 Dental laboratory plaster
6556-1972 Dental impression plaster
6884-1973 Dental silicate cement
6887-1973 Denture base polymer
6888-1973 Dental inlay casting wax
6889-1973 Method for chemical analysis of silver-tin dental amalgam alloy:
6890 Method for chemical analysis of dental gold alloys
(Part I)-1973 Determination of gold, silver, copper, palladium and platinum

(Part II)-1975 Determination of nickel and zinc
7225-1974 Dental cobalt — chromium casting alloys
7348 (Part III)-1975 Glossary of terms relating to dentistry: Part III Dental materials
7425-1974 Dental casting investment for gold alloys
7966-1976 Dental modelling wax
8019-1976 Dental artificial stone
8020-1976 Baseplate? dental
8021-1975 Dental sticky wax
8022-1976 Acrylic resin teeth
8571-1977 Dental porcelain
8815-1978 Tooth designation for dental purposes (two digit system)
8850-1978 Guide for the use of dental materials
8864-1978 Autopolymerizing (acrylic) resins for dental use

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